94. (New) The bone fastener according to claim 83, and including a collet that is threaded internally, wherein the shaft is threaded.

95. (New) The bone fastener according to claim 83, wherein the wing is pivotally engaged with the shaft by way of a hinge.

96. (New) The bone fastener according to claim 83, wherein the wing is pivotally engaged with the shaft by way of a pin hinge.

97. (New) The bone fastener according to claim 83, and including a split collet that that is slidable longitudinally along the shaft when the split collet is expanded and is not slidable longitudinally along the shaft when the split collet is collapsed about the shaft.

98. (New) The bone fastener according to claim 83, and including a split threaded collet, the threads of the collet having at least one long slope surface and at least one short slope surface, wherein the shaft is reciprocally threaded to the threaded collet.

REMARKS

This letter is responsive to an Office Action of 19 February 2004 in which the Examiner rejects the Applicant's response (13 January 2004, paper # 21) to an Office Action mailed 24 April 2003. In that Office Action, the Examiner finds that:

Applicant "deliberately submitted a proposed amendment of the claims that is of a completely different nature than paper #20 amendment".

This letter is also responsive to the Office Action mailed 24 April, 2003. In that Office Action, the Examiner finds that:

Claims 78-81 and 89-92 are rejected for being directed to non-elected species;

Two paragraphs introduced to describe Figs. 71-74 are rejected under 35 U.S.C. 132 for introducing new matter.

Claims 34, 25, 40, 43, 47-50 77, 82 and 84-88 are rejected under 35 U.S.C. 101 for claiming non-statutory subject matter.

The following claims are rejected under 35 U.S.C. 102 (b):

1. Claims 34, 35, 40 and 43 for being anticipated by Dzus (U.S.P. 2,485,531);

2. Claims 34, 35, 40 43 and 83-86 for being anticipated by Tennican (U.S.P. 3,168,50); and

3. Claims 34, 40, 82, 83 and 85 for being anticipated by Ferris U.S.P. 4,865,501)

Response t Office Action mailed 24 April, 2003

I. Scope of elected species

Applicant has cancelled claims 78-81 and 88-92 but reserves the right to recover the material in these claims in future continuation and/or divisional applications related to the instant application.

II. Old Matter presented in a Figure

Page 31, lines 2 and 3 state that the geometry of head embodiment (H4) is "especially useful if the surrounding tissue is very thin and devoid of muscle and/or fat, such as on the forehead or the front of the shin". This statement clarifies Figs. 72 and 73 in that (Claim 34) "the other faces adjoining the first face and contacting the surface each have a smaller area than said first area".

Clearly, Figs. 72 and 73, particularly with the above-noted description, are within the scope defined by Vas-Cath Inc. v Mahurkar 935F.2d 1555, 1563, 19 SUPZ2d 1498 (Fed. Cir. 1998), "Drawings constitute an adequate description if they describe what is claimed and convey to those of skill in the art that the patentee actually invented what is claimed."

III. Statutory Subject Matter

Applicant has amended claims 34 and 82 to remove the following references:

"contacts a ... bone" and "contacts the bone", claim 34; and

"contacts a bone", claim 82,

thereby complying with the examiner's interpretation of 1146 TMOG 24 (1993).

With claims 34, and 82 in allowable form, dependent claims 35, 40, 47-50, 77, 84-88 thereby become allowable.

IV. Adjoining Faces

Applicant has amended claim 34 have been amended to use the word "face" in place of the word "surface".

Webster's Encyclopedic Unabridged Dictionary Updated Version, defines "face" as:

"any of the *bounding* surfaces of a solid figure; a cube has six faces."

On this basis, claim 34 has been broadened and thereby defines a different invention with respect to Dzus (U.S.P. 2,485,531).

V. Fasteners Adapted to be Sterilized

Examiner finds:

i) Claims 34, 35, 40 43 and 83-86 are anticipated by Tennican (U.S.P. 3,168,50); and

ii) Claims 34, 40, 82, 83 and 85 are anticipated by Ferris (U.S.P. 4,865,501).

Applicant has amended independent claims 34, 82 and 83, to specify a fastener "adapted to be sterilized".

That these fasteners must be sterilized prior to implantation as stated on Page 21, lines 14-21 of the instant application:

"The entire fastener is characterized by suitable incorporation of.... materials of long-term biological stability ... well tolerated by the body both during healing and thereafter, and to be extremely unlikely of ... reaction within the joints or the body as a whole."

Non-sterilized fasteners implanted in body tissue cause infections that are not tolerated well by the body, causing infection that can result in death.

Neither Tennican nor Ferris teach devices that are "adapted to be sterilized".

With claims 34, 82 and 83 allowable, dependent claims 35, 40, 43, 84-86 and 93-98 become allowable.

VI. Multiple Dependencies

Applicant has revised claims 47, and 84-88, to remove multiple dependencies, and added claims 93-98, thereby recovering the material sacrificed in removing multiple dependencies of claims 84-88.

Response to Office Action of 19 February 2004

In the subject Office Action, Examiner rejected Applicant's response (13 January 2004, paper # 21) to an Office Action mailed 24 April 2003 and finds that Applicant "deliberately submitted" a response containing errors in the amended claim set. Examiner has

awardedd Applicant "a new time period for reply" of six months as provided by 37 CFR 1.134 and 1.135c.

Applicant respectfully submits that were the proposed claims "inadvertently omitted" and Applicant is entitled to consideration under 37 CFR 1.135c based upon the following:

i) A Patent Office error vis-à-vis the Applicant's timely response to the Office Action mailed 24 April 2003 resulted in a 30 day deadline to formulate the response above-noted inadvertent response. Applicant is neither a Patent Attorney or Patent Agent and due to the tremendous time pressure made *non-substantive* errors.

ii) The claims contain an error in the *cancelled portion* of claim 34 as filed in the RCE of 17 March 2003, but *not* the amended portion of claim 34. Additionally, while claims 48, 49 and 50 were inadvertently included, these claims had been, in fact, "previously cancelled", rendering their inclusion *non-substantive*.

In light of the above inadvertent non-substantive additions and the error of the USPTO, Applicant respectfully requests that no charges or penalties be levied in association with the instant response.

Summary

In view of the above remarks and amendments, a positive IPER is respectfully awaited. In the event that the Examiner believes that there are problems that would make it impossible to allow the claims, the Examiner is respectfully requested to call the undersigned at: (972) 56-758-096 so these issue can be reviewed and/or clarified. Please note that Israel is 7 hours ahead of the US East Coast.

Alternatively, please use the address listed below for sending correspondence to the Applicant.

Respectfully submitted,

Y. FREEDLAND
Inventor and Applicant

April 21, 2004
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Version with Markings to Show Changes Made

IN THE SPECIFICATION

~~-- In an exemplary embodiment, wing 11i1 comprises a body having a contact surface that contacts a portion of bone and at least two adjoining surfaces that adjoin the contact surface and contact the bone. In an exemplary embodiment, the contact surface has a greater area than any adjoining surface.~~

~~Alternatively or additionally, wing 11i1 comprises a contact surface adapted to contact a bone. When the contact surface of wing 11i1 contacts the bone, it has a first extent in a first direction, a second extent in a second orthogonal direction and a third extend in a third orthogonal direction. In an exemplary embodiment, the contact surface lies in a plane defined by the first and second directions of said directions and the third extent is smaller than either the first or second extent.~~

~~Alternatively or additionally, wing 11i1 is pivotably rotatable about an axis, for example passing through pin hinge 11i2 at an end of shaft 111i and wing 11i1 has a contact surface for contacting the bone. In an exemplary embodiment, the axis is external to the contact surface of wing 11i1~~

IN THE CLAIMS

34. (Newly Amended) An orthopedic fastening system adapted to be sterilized for in vivo use, the system, comprising:

a shaft having a ~~pivotal engagement at one end and a~~ wing pivotally engaged ~~with said engagement~~ at one end, the wing comprising a body ~~having a plurality of surfaces, each surface defining an area~~ including:

a first face having a first area adapted for ~~a contact surface having a contact area that contacts a portion of bone~~ contacting a bone surface; and

at least two ~~adjoining surfaces~~ faces that adjoin the first face and adapted for contacting the bone surface, ~~the adjoining surfaces each having a contact edge that~~

Version with Markings to Show Changes Made

IN THE SPECIFICATION

~~-- In an exemplary embodiment, wing 11i1 comprises a body having a contact surface that contacts a portion of bone and at least two adjoining surfaces that adjoin the contact surface and contact the bone. In an exemplary embodiment, the contact surface has a greater area than any adjoining surface.~~

~~Alternatively or additionally, wing 11i1 comprises a contact surface adapted to contact a bone. When the contact surface of wing 11i1 contacts the bone, it has a first extent in a first direction, a second extent in a second orthogonal direction and a third extend in a third orthogonal direction. In an exemplary embodiment, the contact surface lies in a plane defined by the first and second directions of said directions and the third extent is smaller than either the first or second extent.~~

~~Alternatively or additionally, wing 11i1 is pivotably rotatable about an axis, for example passing through pin hinge 11i2 at an end of shaft 111i and wing 11i1 has a contact surface for contacting the bone. In an exemplary embodiment, the axis is external to the contact surface of wing 11i1~~

IN THE CLAIMS

34. (Newly Amended) An orthopedic fastening system adapted to be sterilized for in vivo use, the system, comprising:

a shaft having a ~~pivotal engagement at one end and a~~ wing pivotally engaged ~~with said engagement~~ at one end, the wing comprising a body ~~having a plurality of surfaces, each surface defining an area~~ including:

a first face having a first area adapted for ~~a contact surface having a contact area that contacts a portion of bone~~ contacting a bone surface; and

at least two ~~adjoining surfaces~~ faces that adjoin the first face and adapted for contacting the bone surface, ~~the adjoining surfaces each having a contact edge that~~

~~contacts the bone~~, wherein the other faces adjoining the first face and contacting the bone surface each have a smaller ~~the contact surface has a greater~~ area than said first area ~~any adjoining surface~~.

35. (Previously Amended) The orthopedic fastening system according to claim 34, and including a collet that is threaded internally, wherein the shaft is threaded.

36-39 (Previously Cancelled)

40. (Previously Amended) The orthopedic fastening system according to claim 34, wherein the wing is pivotally engaged with the shaft by way of a hinge.

41-42 (Previously Cancelled)

43. (Previously Amended) The orthopedic fastening system according to claim 34, wherein the wing is pivotally engaged with the shaft by way of a pin hinge.

44-46 (Previously Cancelled)

47. (Newly Amended) The orthopedic fastening system according to ~~any one of~~ claims 34, ~~35, 40 and 43,~~ and including a split collet that is slidable longitudinally along the shaft when the split collet is expanded and is not slidable longitudinally along the shaft when the split collet is collapsed about the shaft.

48-76 (Previously canceled)

77. (Previously Added) The orthopedic fastening system according to claim 34, and including a split threaded collet, the threads of the collet having at least one long slope surface and at least one short slope surface, wherein the shaft is reciprocally threaded to the threaded collet.

~~contacts the bone~~, wherein the other faces adjoining the first face and contacting the bone surface each have a smaller ~~the contact surface has a greater~~ area than said first area ~~any adjoining surface~~.

35. (Previously Amended) The orthopedic fastening system according to claim 34, and including a collet that is threaded internally, wherein the shaft is threaded.

36-39 (Previously Cancelled)

40. (Previously Amended) The orthopedic fastening system according to claim 34, wherein the wing is pivotally engaged with the shaft by way of a hinge.

41-42 (Previously Cancelled)

43. (Previously Amended) The orthopedic fastening system according to claim 34, wherein the wing is pivotally engaged with the shaft by way of a pin hinge.

44-46 (Previously Cancelled)

47. (Newly Amended) The orthopedic fastening system according to ~~any one of~~ claims 34, ~~35, 40 and 43,~~ and including a split collet that is slidable longitudinally along the shaft when the split collet is expanded and is not slidable longitudinally along the shaft when the split collet is collapsed about the shaft.

48-76 (Previously canceled)

77. (Previously Added) The orthopedic fastening system according to claim 34, and including a split threaded collet, the threads of the collet having at least one long slope surface and at least one short slope surface, wherein the shaft is reciprocally threaded to the threaded collet.

78-81 (Cancelled)

82. (Newly Amended) A bone fastener, adapted to be sterilized for in vivo use, comprising a shaft and a wing that is pivotally attached to the shaft, the wing having:

a first insertion position in which a contact surface of the wing, is substantially parallel to the shaft,

a second deployed position in which the contact ~~a~~ surface of the wing is substantially oblique to the shaft ~~contacts a bone surface~~, wherein in the wing has:

a first extent in a first direction;

a second extent in a second orthogonal direction; and

a third extend in a third orthogonal direction, wherein

the contact surface lies in a plane defined by the first and second directions of said directions and wherein, the third extent is smaller than either the first or second extent.

83. (Newly Amended) A bone fastener adapted to be sterilized for in vivo use, comprising:

a shaft; and

a wing body pivotably rotatable at an end of the shaft about an axis, and having a contact surface for contacting the bone, wherein

the axis is external to the contact surface.

84. (Newly Amended) The ~~orthopedic fastening system~~ bone fastener according to claim 82 ~~or claim 83~~ and including a collet that is threaded internally, wherein the shaft is threaded.

85. (Newly Amended) The ~~orthopedic fastening system~~ bone fastener according to claim 82 ~~or claim 83~~, wherein the wing is pivotally engaged with the shaft by way of a hinge.

86. (Newly Amended) The ~~orthopedic fastening system~~ bone fastener according to claim 82 ~~or claim 83~~, wherein the wing is pivotally engaged with the shaft by way of a pin hinge.

78-81 (Cancelled)

82. (Newly Amended) A bone fastener, adapted to be sterilized for in vivo use, comprising a shaft and a wing that is pivotally attached to the shaft, the wing having:

a first insertion position in which a contact surface of the wing, is substantially parallel to the shaft,

a second deployed position in which the contact ~~a~~ surface of the wing is substantially oblique to the shaft ~~contacts a bone surface~~, wherein in the wing has:

a first extent in a first direction;

a second extent in a second orthogonal direction; and

a third extend in a third orthogonal direction, wherein

the contact surface lies in a plane defined by the first and second directions of said directions and wherein, the third extent is smaller than either the first or second extent.

83. (Newly Amended) A bone fastener adapted to be sterilized for in vivo use, comprising:

a shaft; and

a wing body pivotably rotatable at an end of the shaft about an axis, and having a contact surface for contacting the bone, wherein

the axis is external to the contact surface.

84. (Newly Amended) The ~~orthopedic fastening system~~ bone fastener according to claim 82 ~~or claim 83~~ and including a collet that is threaded internally, wherein the shaft is threaded.

85. (Newly Amended) The ~~orthopedic fastening system~~ bone fastener according to claim 82 ~~or claim 83~~, wherein the wing is pivotally engaged with the shaft by way of a hinge.

86. (Newly Amended) The ~~orthopedic fastening system~~ bone fastener according to claim 82 ~~or claim 83~~, wherein the wing is pivotally engaged with the shaft by way of a pin hinge.

87. (Newly Amended) The ~~orthopedic fastening system~~ bone fastener according to claim 82 ~~or claim 83~~, and including a split collet that that is slidable longitudinally along the shaft when the split collet is expanded and is not slidable longitudinally along the shaft when the split collet is collapsed about the shaft.

88. (Newly Amended) The ~~orthopedic fastening system~~ bone fastener according to claim 82 ~~or claim 83~~, and including a split threaded collet, the threads of the collet having at least one long slope surface and at least one short slope surface, wherein the shaft is reciprocally threaded to the threaded collet.

89-92 (Cancelled)

93. (New) The orthopedic fastening system according to claim 34, wherein the third extent includes at least one surface having at least one edge, the edge being adjoined to the contact surface, such that when the contact is deployed against a facing, only the at least one edge ~~the adjoining faces are adapted to~~ contact the facing ~~when deployed, only at edges of the faces~~.

94. (New) The bone fastener according to claim 83 and including a collet that is threaded internally, wherein the shaft is threaded.

95. (New) The bone fastener according to claim 83, wherein the wing is pivotally engaged with the shaft by way of a hinge.

96. (New) The bone fastener according to claim 83, wherein the wing is pivotally engaged with the shaft by way of a pin hinge.

97. (New) The bone fastener according to claim 83, and including a split collet that that is slidable longitudinally along the shaft when the split collet is expanded and is not slidable longitudinally along the shaft when the split collet is collapsed about the shaft.

87. (Newly Amended) The ~~orthopedic fastening system~~ bone fastener according to claim 82 ~~or claim 83~~, and including a split collet that that is slidable longitudinally along the shaft when the split collet is expanded and is not slidable longitudinally along the shaft when the split collet is collapsed about the shaft.

88. (Newly Amended) The ~~orthopedic fastening system~~ bone fastener according to claim 82 ~~or claim 83~~, and including a split threaded collet, the threads of the collet having at least one long slope surface and at least one short slope surface, wherein the shaft is reciprocally threaded to the threaded collet.

89-92 (Cancelled)

93. (New) The orthopedic fastening system according to claim 34, wherein the third extent includes at least one surface having at least one edge, the edge being adjoined to the contact surface, such that when the contact is deployed against a facing, only the at least one edge ~~the adjoining faces are adapted to~~ contact the facing ~~when deployed, only at edges of the faces~~.

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96. (New) The bone fastener according to claim 83, wherein the wing is pivotally engaged with the shaft by way of a pin hinge.

97. (New) The bone fastener according to claim 83, and including a split collet that that is slidable longitudinally along the shaft when the split collet is expanded and is not slidable longitudinally along the shaft when the split collet is collapsed about the shaft.

98. (New) The bone fastener according to claim 83, and including a split threaded collet, the threads of the collet having at least one long slope surface and at least one short slope surface, wherein the shaft is reciprocally threaded to the threaded collet.